

REMARKS

Applicants respectfully request entry of the amendment and reconsideration of the claims. Claims 2-5 have been canceled. Claim 1 has been amended to further clarify the claimed invention. Accordingly, claims 1 and 6-8 are pending after entry of this amendment.

Applicants submit the claim amendment is supported throughout the specification, including at page 2, lines 30-32, at page 3, lines 34-36, at page 7, lines 20-21, and Figures 1 and 3, and do not raise any issues of new matter.

Interview

Applicants conducted a telephonic interview of the Examiner on August 8, 2003. Examiner Saucier and Applicants' representatives Douglas Mueller and Eric DeMaster participated in the interview. Claims 1 and 2 and the prior art cited by the Examiner under 35 U.S.C. § 102(b) were discussed. No agreement with respect to the claims was reached. In responding to the outstanding Office Action, Applicants agreed to present arguments and amendments in an effort to advance prosecution. Applicants thank the Examiner for the opportunity to discuss the pending application.

Subject Matter

The Examiner rejected claims 1-6 under 35 U.S.C. § 101 as directed to non-statutory subject matter. Claim 1 has been amended to claim the enzyme in isolated form. Applicants respectfully request withdrawal of the non-statutory subject matter rejection.

Deposit

The Examiner rejected claims 3 and 5 under 35 U.S.C. § 112, first paragraph, as lacking enablement because the claimed bacterial strains are not publicly available. Although claims 3 and 5 have been canceled, this rejection is discussed insofar as it might apply to claim 1.

To satisfy the deposit requirement for deposits made under the Budapest Treaty, the Examiner required a statement that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of

the patent. A Communication Regarding Deposit is submitted herewith. Applicants submit the Communication satisfies the deposit requirements under 37 CFR §§ 1.803-1.808.

Based on the forgoing, Applicants respectfully request withdrawal of the enablement rejection.

Novelty

1) The Examiner rejected claims 1-7 under 35 U.S.C. § 102(b) as anticipated by WO 98/48043. Applicants respectfully traverse this rejection.

To anticipate Applicants' claims, WO 98/48043 must teach every element of the pending claims. MPEP § 2131. Applicants' claims are directed to an enzyme derived from *Corynebacterium ureolyticum* KDK1002 (FERM P-17135) or *Pseudomonas alcaligenes* KDK1001 (FERM P-17133). WO 98/48043 does not teach an enzyme derived from *Corynebacterium ureolyticum* KDK1002 (FERM P-17135) or *Pseudomonas alcaligenes* KDK1001 (FERM P-17133) nor does WO 98/48043 teach that such an enzyme releases an amino acid having a glycosylated α -amino group from a glycosylated protein or a glycosylated peptide.

Based on the forgoing, Applicants respectfully request withdrawal of this anticipation rejection.

2) The Examiner rejected claims 1 and 8 under 35 U.S.C. § 102(b) as anticipated by WO 97/20039. Applicants respectfully traverse this rejection.

To anticipate the claims, WO 97/20039 must teach every element of the claims. MPEP § 2131. The protease disclosed in WO 97/20039 is not derived from *Corynebacterium ureolyticum* or *Pseudomonas alcaligenes*. WO 97/20039 therefore does not teach every element of the claims. Accordingly, Applicants respectfully request withdrawal of this anticipation rejection.

3) The Examiner rejected claims 1 and 4-6 under 35 U.S.C. § 102(b) as anticipated by Shin et al. The Examiner asserts the protease disclosed by Shin et al. inherently anticipates Applicants claims because the prior art enzyme is obtained from the same genus and species and shares the property of being able to hydrolyze proteins. Applicants respectfully traverse this rejection.

Inherency may not be established by probabilities or possibilities. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981). "In relying upon a theory of inherency, the Examiner must provide

a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQD2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

The Examiner asserts the enzyme disclosed by Shin et al. may be the same as the enzyme claimed by Applicants because the enzyme disclosed in the reference possesses inherent characteristics that might not be displayed in the tests used in the reference. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). The Examiner has provided no basis in fact or technical reasoning supporting the determination that specific α -glycated amino acid releasing activity necessarily flows from the ability of the prior art protease to hydrolyze various proteins. The mere possibility that the enzyme disclosed by Shin et al. might have specific α -glycated amino acid releasing activity is not enough to meet the Examiner's burden. Therefore, the Examiner has failed to establish that the protease disclosed in Shin et al. inherently anticipates the claimed enzyme.

Based on the forgoing, Applicants submit the Shin et al. reference does not teach every element of the claim, either expressly or inherently. Withdrawal of the anticipation rejection is respectfully requested.

4) The Examiner rejected claims 1, 4, and 6 under 35 U.S.C. § 102(b) as anticipated by JP 50-19628. The Examiner asserts the protease disclosed by JP 50-19628 inherently anticipates Applicants claims because the prior art enzyme is obtained from the same genus and shares the property of being able to hydrolyze hemoglobin. Applicants respectfully traverse this rejection.

As discussed above, in order to rely on inherency the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQD2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Probabilities or possibilities are not sufficient to establish inherency. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

The Examiner has provided no basis in fact or technical reasoning supporting the determination that specific α -glycated amino acid releasing activity necessarily flows from the ability of the prior art protease to hydrolyze hemoglobin. Applicants' claims require the enzyme

be derived from *P. alcaligenes*. The protease disclosed in JP 50-19628 was derived from *P. aeruginosa*.

+The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). The hemoglobin hydrolyzed by the protease disclosed in JP 50-19628 does not appear to be glycosylated. Consequently, one skilled in the art may only speculate as to whether the protease in the reference would release an amino acid having a glycosylated α -amino group.

The mere possibility that the enzyme disclosed by JP 50-19628 might have specific α -glycosylated amino acid releasing activity is not enough to meet the Examiner's burden. Therefore, the Examiner has failed to establish that the protease disclosed in JP 50-19628 inherently anticipates the claimed enzyme. Withdrawal of this anticipation rejection is respectfully requested.

5) The Examiner rejected claims 1, 4, and 6 under 35 U.S.C. § 102(b) as anticipated by JP 63-279782. Applicants respectfully traverse this rejection. Applicants submit JP 63-279782 does not teach all of the claim limitations because the reference does not disclose, either expressly or inherently, an isolated enzyme derived from *Corynebacterium ureolyticum* that has specific α -glycosylated amino acid releasing activity.

To anticipate the claims, JP 63-279782 must teach every element of the claims either expressly or inherently. MPEP § 2131. The reference does not expressly teach an enzyme that releases an amino acid having a glycosylated α -amino group from a glycosylated protein or a glycosylated peptide.

With respect to inherency, the Examiner must, as discussed above, provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The burden does not shift to the Applicant unless the Examiner has established a prima facie showing of anticipation. MPEP § 2112.

The Examiner has not provided any objective evidence or technical reasoning supporting the conclusion of inherency. JP 63-279782 does not teach or suggest an enzyme having glycosylated amino acid releasing activity. Rather, the reference discloses an alkaline protease isolated from

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several species of *Corynebacterium* that has significant casein decomposition activity in a solution containing detergent. Moreover, the alkaline protease disclosed by the reference has a molecular weight of about 14,600 Daltons. In contrast, the enzyme claimed by Applicants has a molecular weight of about 40,000 to 50,000 Daltons.

Based on the forgoing, Applicants submit the Examiner has failed to establish a prima facie case of anticipation. Withdrawal of the rejection is respectfully requested.

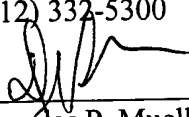
Conclusion

In view of the above amendments and remarks, favorable reconsideration in the form of Notice of Allowance is respectfully requested. The Examiner is invited to telephone the undersigned for clarification of any of the amendments and remarks or to otherwise facilitate prosecution of the application.

Respectfully submitted,

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